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July 12, 2018

The Honorable Gregory M. Sleet  
United States District Court  
For the District of Delaware  
844 North King Street  
Wilmington, DE 19801

*VIA ELECTRONIC FILING*

Re: *Genentech, Inc. et al. v. Celltrion, Inc. et al.*,  
C.A. No. 18-095 (GMS)

Dear Judge Sleet:

This firm, together with Wilmer Cutler Pickering Hale and Dorr LLP and Durie Tangri LLP, represents Plaintiffs Genentech, Inc., Hoffmann-La Roche Inc., and City of Hope (collectively, “Genentech”) in the above-referenced matter against Defendants Celltrion, Inc., Celltrion Healthcare Co., Ltd., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals International GmbH (collectively, “Celltrion”). We write to inform your Honor that, out of an abundance of caution, Genentech has filed a new patent infringement lawsuit against Celltrion in this Court alleging infringement of the same patents that are at issue in this case. *See Genentech, Inc. v. Celltrion, Inc.*, C.A. No. 18-1025 (D. Del. filed July 11, 2018). Genentech’s new complaint is designated as related to this lawsuit (and to the other cases involving Genentech’s biosimilar products that are pending before this Court).

Genentech filed the new case to preserve its rights in light of novel and improper interpretations of the Biologics Price Competition and Innovation Act (“BPCIA”) that Celltrion has advanced in recent correspondence with Genentech. The BPCIA creates a system of pre-suit information exchanges called the “patent dance.” Genentech and Celltrion started the patent dance last fall, but Celltrion prematurely ended it in January by filing a declaratory judgment complaint in the Northern District of California. Genentech responded by filing this case. This case is moving forward, but Celltrion’s California case has been dismissed as statutorily barred by Celltrion’s failure to complete certain steps of the patent dance. *Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-274, 2018 WL 2448254, at \*5 (N.D. Cal. May 9, 2018). Celltrion was required to complete those steps in January, but it did not.

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Last month—after Celltrion’s California case was dismissed and nearly six months after the relevant patent-dance deadlines had passed—Celltrion sent Genentech two letters purporting to complete the patent-dance steps that it failed to complete in January. Genentech’s position is that these letters were untimely and should create no obligations for Genentech. But if Celltrion were somehow able to resurrect the patent dance, the BPCIA might have required Genentech to bring a new action for infringement by July 11, 2018. *See* 42 U.S.C. § 262(l)(6). Celltrion has argued, in other cases, that Genentech might face penalties under the BPCIA for failing to do so. Accordingly, in an abundance of caution, Genentech filed its new complaint on July 11, 2018, to preserve its rights.

The BPCIA creates statutory penalties that may be triggered by dismissal of a BPCIA lawsuit (e.g., limitations on a patent holder’s remedies under 35 U.S.C. § 271(e)(6)). Genentech will therefore ask the Court to consolidate its new case with this one, either by stipulation or by motion. Genentech respectfully requests that the Court take no action that might result in the dismissal of its new complaint until consolidation is addressed.

We are available to discuss these issues with the Court at its convenience.

Respectfully,

*/s/ Maryellen Noreika*

Maryellen Noreika (#3208)

MN/dlw

cc: All Counsel of Record (Via Electronic Mail)